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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,290	REDMOND ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-24 and 26-31* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,9,11-24 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received and entered on September 8, 2009. All evidence and arguments have been fully considered. Claims 10 and 25 are cancelled. Claims 1-9, 11-24 and 26-31 are pending. Claims 4-7 have been withdrawn due to a prior requirement for restriction. Claims 1-3, 8-9, 11-24 and 26-31 are examined on the merits in this office action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 8-9, 11-24 and 26-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Westerlund et al. (Carbohydrate Polymers, 1993, 20:115-123, cited in previous action) or Bhatty (US 5,518,710, cited in previous action), in view of Jamas et al. (US 5,622,939). Claim 1 recites a pharmaceutical composition consisting essentially of at least about 75% beta (1-3) beta (1-4) glucan (referred to as beta-glucan in this office action) having a particle size of equal to or less than 0.2 microns, less than 10% ash impurities, less than 10% protein impurities, and less than 5% lipid impurities, and a botanical extract or a pharmaceutically active agent. Claims 2 and 3 recite that the botanical abstract is an extract of oat grain. Claims 8 and 9 recite that the beta glucan is derived from a cereal grain or a part thereof, specifically a cultivar of oat. Claim 11 recites that the beta-glucan composition has a purity of at least about 92% and contains less than 3.5% ash impurities, less than 3.5% protein impurities, and less than 1% lipid impurities, and a clarity value from about 5 to about 10 NTU. Claim 13 recites that the beta-glucan composition is produced according to a method comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a value of pH between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight % beta glucan; (ii)

removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract comprising beta-glucan having a particle size of equal to or less than 0.2 micron wherein the step comprises filtration with a cutoff size of 0.2 micron; (iii) adding from about 10% to about 25% weight/weight (w/w) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 14 and 15 recite that the alcohol of claim 13 is selected from methanol, ethanol or isopropanol, specifically ethanol. Claim 16 further limits claim 13 by reciting the limitation that the step of removing the particulate material further comprises the following step prior to microfiltration: one, or more than one step of adding flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; and digesting starch material in said extract. Claim 17 further limits claim 16 by reciting the limitation that the starch material is digested with an enzyme. Claim 18 further limits claim 17 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claims 19 and 20 recite the method of claim 18 wherein, following the digestion of the starch material, the enzyme is inactivated, specifically by acidifying the neutralized solution. Claims 21 and 22 further limit claim 17 by reciting the limitation that the enzyme is an amylase, specifically one which requires a calcium cofactor. Claim 23 further limits claim 1 by reciting that the cereal is selected from the group recited in the claim. Claim 24 further limits claim 13 by reciting the limitation that the pH of the alkaline solution is from about 9 to about 10. Claim 26 further limits claim

13 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 27 further limits claim 13 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding about 10% to about 20% (w/w) of the C_1-C_4 alcohol to the aqueous solution, and isolating the beta glucan. Claims 28-31 recite compositions with the elements of previous claims containing a botanical extract or a pharmaceutically active agent; and a pharmaceutically acceptable diluent or carrier.

5. Westerlund teaches a composition comprising beta-glucan extracted from oat bran (abstract). The glucan of Westerlund has a purity of up to 99% (abstract). Because the beta glucan of Westerlund is not 100% pure, the composition would comprise another extract from oat, i.e. a botanical extract. Although Westerlund does not disclose the specific percentages of ash, protein and lipid impurities, it can be inferred that a composition which is 99% pure would not contain more than 1% of any impurity, and would have the claimed clarity value. Further, although the methods for the production of the composition of Westerlund are not identical to the methods by which the claimed composition is made, the composition of Westerland does not appear to be different from the claimed composition. Therefore, the composition of Westerlund would have the same inherent properties of the claimed composition.

6. Bhatty teaches a composition comprising beta-glucan extracted from oat bran (col. 5, line 50-col. 6, line 22). The glucan of Bhatty has a purity of at least about 80% and contains 0.5% nitrogen and about 3.7 percent ash (col. 9, table III). Because the

beta glucan of Bhatty is not 100% pure, the composition would comprise another extract from oat, i.e. a botanical extract. Although Bhatty does not disclose the specific percentages of protein and lipid impurities, the method of making the beta-glucan in the composition of Bhatty is nearly identical to the disclosed method of producing the claimed composition. Therefore, the composition of Bhatty would have the same inherent properties of the claimed composition. Specifically, Bhatty teaches that the beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) is extracted from milled cereal grain (including cultivars of oat; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14 (col. 3, lines 22-26), removing insoluble (particulate) material by centrifugation, dialysis or filtration (col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C_1 to C_4 alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting materials that comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by nearly the same methods

as recited in the claims in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range, or the claimed range would have been arrived at in the course of routine experimentation. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches that the pH of the alkaline solution can be adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution, precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). Although Bhatty does not teach the inactivation of the amylase, specifically one which does not require a calcium cofactor, using an acid, or the claimed period of extraction by which the claimed composition is produced, the composition of Bhatty appears to be nearly identical to the claimed composition.

7. Although nearly all of the claimed elements are taught by Westerlund or Bhatty, neither of the references specifically teaches the microfiltration of the beta-glucan to produce a beta-glucan with the claimed particle size.

8. Jamas teaches a method for the extraction of beta-glucan wherein soluble beta glucan can be separated from insoluble beta glucan by ultrafiltration to produce a

pharmaceutical product comprising beta-glucan (abstract, col. 6, lines 16-32). The reference teaches that filtration using a 0.2 micron filter is desirable because is an acceptable method for sterilizing pharmaceutical products (col. 6, line 67-col. 7, line 2, col. 11, lines 48-51).

9. At the time of the invention, beta-glucan containing compositions produced by nearly all the same steps and comprising nearly all of the same properties were known, as taught by Westerlund and Bhatty. It was further known that microfiltration could be performed with beta-glucan compositions to produce compositions containing beta-glucan particles of specific sizes, as taught by Jamas. One of ordinary skill in the art would have been motivated to combine these teachings because compositions comprising beta-glucan were known in the art at the time of the invention to be desirable, as taught by Jamas, who further teaches that it is was known to be desirable to purify such products using filtration with a cutoff of 0.2 microns. One of ordinary skill in the art would have had a reasonable expectation of success combining the teachings of the prior art to arrive at the claimed invention because filtration, particularly microfiltration, of beta-glucan compositions was known in the art at the time of the invention, as taught by the cited references. Note that some of the claims are drawn to a product claim that is defined in terms of the process by which it is made. The rationale has provided to show that the claimed product appears to be the same or similar to that of the prior art, although it may be produced by a different process. It would therefore have been obvious for one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

10. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

11. Applicant's arguments filed September 9, 2009 have been fully considered but they are not persuasive. Applicant argues that the combined references do not render the claimed invention obvious. Specifically, applicant argues the preparation of a composition using the combined references would result in the preparation of a product with a narrower range of particle sizes than the composition recited in the claims. However, the motivation to prepare the composition as claimed is provided in the rejections above. Briefly, one of ordinary skill in the art would have been motivated to use a microfiltration with a cutoff size of 0.2 microns in the method of Bhatty to produce the claimed composition because it was known in the art at the time of the art that filtration could be used to separate soluble beta glucan from insoluble beta glucan, as taught by Bhatty, Potter and Jamas; Potter teaches the use of a 0.2 micron filter for this purpose (col. 6, lines 26-32) and Jamas teaches the use of ultrafiltration and a 0.2 micron filter for sterilization. Because a filter for the production of particles with the cutoff size recited in the claims was known in the art at the time of the invention to be useful for the separation of insoluble and soluble beta glucan, as disclosed by Potter, one of ordinary skill in the art would have been motivated to use a 0.2 micron filter in the filtration step of Bhatty. The motivation to combine the teachings to arrive at the claimed method is discussed in the rejections above. Although applicant argues that the

combined method would use the ultrafiltration of Jamas to prepare a size fraction that differs from that claimed in the instant application, it is noted that the reference provides motivation to prepare the composition as claimed. Therefore, the cited references render obvious the claimed invention and applicant's argument has not been found to be persuasive.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651